



Office for Human Research Protections
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August 18, 2005

Charles F. Zukoski
Vice-Chancellor for Research
University of Illinois
at Urbana-Champaign
Swanlund Building, Fourth Floor
601 East John Street
Champaign, IL 61820-5711

**RE: Human Research Subject Protections Under Multiple Project Assurance M-1004 and
Federalwide Assurance FWA-8584**

Research Project:	Study of HIV/AIDS Perception, Attitudes, and Knowledge Among University of Illinois Students
Principal Investigator:	Jerry Ogbudimpka, Ph.D.
Research Project:	Study of 4% Lidocaine Intranasally to Treat Migraine
Principal Investigator:	Santiago Ulloa, M.D.
Research Project:	Name the Bug: Organism Identification for College Health Clinicians
Principal Investigator:	Robert Palinkas, M.D.
Research Project:	Diabetes on Campus: Working Toward Evidence-Based Practice in a College Environment
Principal Investigator:	David Lawrence, M.D.
Research Project:	Assessment, Implementation and Evaluation of Men's Health Clinic
Principal Investigator:	Connie Maske
Research Project:	Teaching Students to Manage Their Non-Traumatic Back and Neck Pain

Principal Investigator: Melinda Flegel

Research Project: Ankle Sprains: A Simple Standardized Approach to Effective Care

Principal Investigator: Melinda Flegel

Dear Mr. Zukoski:

The Office for Human Research Protections (OHRP) has reviewed the University of Illinois at Urbana-Champaign's (UIUC) August 5, 2005 report submitted in response to OHRP's letter of June 30, 2005. In addition, OHRP has reviewed a report from Dr. Robert Palinkas, Director, McKinley Health Clinic (MHC), dated August 5, 2005.

After reviewing these reports, OHRP finds no compelling reason to alter its previous determinations. OHRP remains particularly concerned that research activities may continue to be conducted at the MHC under the guise of quality improvement programs. UIUC has indicated that a number of these programs now have current IRB approval and has initiated corrective actions to address OHRP's previous determinations. These corrective actions include:

(i) Audits of the MHC will be conducted annually for the next three years; (ii) the Director of the IRB office will serve as a member of the MHC Research and Grants Compliance Committee; and (iii) all staff at the MHC will be required to attend human subjects research training at least annually. OHRP finds that the corrective actions described in UIUC's May 25, 2005 report adequately address the determinations made in OHRP's March 14, 2005 letter and are appropriate under the UIUC FWA. Furthermore, OHRP finds that UIUC has adequately addressed the additional questions and concerns raised in OHRP's March 14, 2005 letter.

As a result of these determinations, there should be no need for further involvement of OHRP in this matter. However, please note that OHRP plans to conduct an on-site evaluation of UIUC's system for the protection of human subjects in the next 12 - 24 months.

Please do not hesitate to contact me should you have any questions.

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Van Anderson, Associate Vice-Chancellor for Research, UIUC
Ms. Susan Keehn, IRB Director, UIUC
Dr. Eva Pomerantz, IRB Chair, UIUC
Dr. Jerry Ogbudimpka, UIUC
Dr. Robert Palinkas, UIUC

Dr. David Lawrence, UIUC
Ms. Connie Maske, UIUC
Ms. Melinda Flegel, UIUC
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borrer, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP